510(k) summary

510(k): K116869

CARA

March 2011

JUL 14 2011

1. Applicant Information

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2. Device Information

Classification names: Picture Archiving and Communications System
Device classification: Class II
Regulation numbers: 21 CFR 892.2050
Product codes: NFJ
Proprietary name: CARA

3. Predicate Device

The predicate device is the Topcon IMAGEnet Professional PC Software System, cleared under K082364.

4. Description of device

CARA is a software platform that collects, enhances, stores, and manages color fundus images. Through the internet, CARA software collects and manages color fundus images from a range of approved computerized digital imaging devices. CARA enables a real-time review of retinal image data (both original and enhanced) from an internet-browser-based user interface to allow authorized users to access and view data saved in a centralized database. The system utilizes state-of-the-art encryption tools to ensure a secure networking environment.

5. Indications for use

CARA is a comprehensive software platform intended for importing, processing, and storing of color fundus images as well as visualization of original and enhanced image through computerized networks.

6. Substantial Equivalence

The claim of substantial equivalence to the Topcon IMAGEnet Professional PC Software System is based on similar intended uses to collect, store, enhance and transfer digital retinal images from computerized imaging devices through computerized networks.

The table below provides a comparison between the predicate device and the CARA device.

	Topcon IMAGEnet	Diagnos CARA
Software Only	√	√
Web Based Platform	x	√
Non-mydriatic Capture Device Images Processing	√	√
Image Data Management	√	√
Fundus Image Only	√	√
File Import	√	√
Color Fundus Image Enhancement	x	√
Black &White Fundus Image Enhancement	√	x
Linear Distance and Area Measurement	√	x
Image Annotation & Measurement	√	x

√ = present

x = absent

CARA shares many similar technological characteristics as the predicate device, both in terms of the manner in which images are captured, processed, and stored, as well as the operation of the device by the intended user.

The results of performance and software validation and verification testing demonstrate that CARA performs as intended and meets the specifications. This supports the claim of substantial equivalence

Any minor difference in operation does not raise additional new questions about safety and effectiveness. CARA raises the same issues of safety and effectiveness as the predicate device.

7. Clinical data:

Since the CARA system currently is not a stand-alone tool, does not make any diagnostic claims and does not replace the existing retinal images or the treating physician, the sponsor believes that the software testing and validation presented in this 510(k) are sufficient and that there is no need for a clinical trial.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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JUL 14 2011

Re: K110869
Trade/Device Name: CARA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: June 15, 2011
Received: June 16, 2011

Dear Mr. Shapiro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Keona Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110869

Device Name: CARA

Indications for Use:

CARA is a comprehensive software platform intended for importing, processing, and storing of color fundus images as well as visualization of original and enhanced image through computerized networks.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K110869